REMARKS/ARGUMENTS

INTRODUCTORY COMMENTS:

In the non-final Office Action under reply, the Examiner entered the Preliminary Amendments dated May 30, 2002 and December 6, 2002. In addition, the Examiner required restriction between two groups of claims, as follows:

Group I: Claims 1-25, 28-36, 38-53, 94, and 96, drawn to an anastomosis stent; and

Group II: Claims 54-68, 71-79, 81-93, and 95, drawn to a tissue plug.

Although a provisional election of Group I was made by phone with traverse, applicants hereby affirm the election of Group I and withdraw the traverse.

In addition, the Examiner acknowledged receipt of the references identified in the Information Disclosure Statement (IDS) mailed on May 30, 2002, but noted that the references were illegible as a result of irradiation. In response, applicants hereby submit a duplicate of the papers and references associated with the IDS, request consideration of the references, and ask for the return of an initialed PTO-1449 form indicating that the references have been reviewed and made of record.

Claims 42-53 stand under 35 U.S.C. §112, second paragraph, as indefinite. In particular, the Examiner states that the term "the aperture" in claim 42 lacks antecedent basis and that the terms "CIS" and "CSF" in claim 47 are unclear.

The Examiner also issued the following art-based claim rejections:

(1) Claims 1, 2, 6, 7, 12-16, 28-32, 36, 38, and 39 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,001,123 to Lau;

(2) Claims 1, 12, 28-33, 35, 38, and 39 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,874,500 to Rhee et al.;

(3) Claims 1, 2, 12, 21, and 25 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,690,684 to McGreevy et al.;

(4) Claims 1-5, 8, 17, 18, 20, 41-43, and 53 stand rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,056,762 to Nash et al. in view of U.S. Patent No. 5,180,392 to Skeie et al.;

(5) Claims 9-11 stand rejected under 35 U.S.C. §103(a) as obvious over Rhee et al.;

(6) Claim 19 stands rejected under 35 U.S.C. §103(a) as obvious over Nash et al. in view of Skeie et al. and U.S. Patent No. 5,944,019 to Knudson et al.;

(7) Claims 21-24 stand rejected under 35 U.S.C. §103(a) as obvious over Rhee et al. in view of U.S. Patent No. 5,527,324 to Krantz et al.;

(8) Claims 40 and 44 stand rejected under 35 U.S.C. §103(a) as obvious over Nash et al. in view of Skeie et al. and U.S. Patent No. 5,141,516 to Detweiler et al.;

(9) Claims 44-50, 94, and 96 stand rejected under 35 U.S.C. §103(a) as obvious over Nash et al. in view of Skeie et al., Detweiler et al., and U.S. Patent No. 6,495,127 to Wallace et al.; and

(10) Claims 51 and 52 stand rejected under 35 U.S.C. §103(a) as obvious over Nash et al. in view of Skeie et al., Detweiler et al., and U.S. Patent No. 4,740,534 to Matsuda et al.

The rejections are addressed in part by the above amendments to the claims and are otherwise traversed for reasons that will be discussed in detail below.

THE ABOVE AMENDMENTS:

Claims 1, 94 and 96 have been amended to clarify that stents recited therein are ***resorbable by a patient within a time period in the range of about a few minutes up to about 90 days.*** That is, the ***stents themselves***, not just a material forming the stents, are resorbable. Support for this amendment can be found in the specification, e.g., on page 3, lines 20-21.

Claim 42 has been amended for clarification purposes and to provide proper antecedent basis for the term "the aperture." Similarly, claim 47 has been amended to clarify that the terms "CIS" and "CSF" refer to "collagen in solution" and "colony stimulating factor," respectively.

Thus, no new matter has been introduced by way of any of these amendments, and entry thereof is respectfully requested.

STATUS OF THE CLAIMS:

Upon entry of the amendments, claims 1-25, 28-36, 38-68, 71-79, and 81-96 are pending, claims 54-68, 71-79, 81-93, and 95 are withdrawn from consideration, claims 1, 42, 47, 94, and 96 are amended, and claims 2-25, 28-36, 38-41, 43-46, 48-68, 71-79, 81-93, and 95 remain unchanged from the Preliminary Amendment submitted on December 6, 2002.

THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION:

Claims 42-53 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. In support of this rejection, the Examiner states that the term "the aperture" in claim 42 lacks antecedent basis and that the terms "CIS" and "CSF" in claim 47 are unclear. In response, applicants have amended claims 42 and 47 according to the Examiner's suggestions. Accordingly, withdrawal of these formal rejections is warranted and respectfully requested.

THE 35 U.S.C. §102(E) REJECTION OVER LAU:

Claims 1, 2, 6, 7, 12-16, 28-32, 36, 38, and 39 stand rejected under 35 U.S.C. §102(e) as anticipated by Lau. Citing column 15, lines 23-31 and lines 33-36, the Examiner characterizes Lau as disclosing a stent that is comprised of first second termini that is sized to be inserted into an opening in a vessel of a patient, and the stent is comprised of a polyethylene glycol of a molecular weight of about 100 to about 20,000 daltons conjugated to a collagenic material. The Examiner also states that Lau discloses a stent having a diameter of 1-8 mm, depending on the location of the stent. While recognizing that Lau does not expressly disclose the element regarding the resorbability time associated with the stent, the Examiner nevertheless states that the Lau stent material "is the same as claimed and inherently ... will function in the same fashion."

In response, applicants point out that it is axiomatic that a cited reference must disclose each and every element of a claim to anticipate the claim. *In re Spada,* 15 USPQ2d 1655 (Fed. Cir. 1990). Unless there is "identity of invention," such that all claim elements are disclosed in a single reference, there can be no anticipation under 35 U.S.C. §102. Here, the claims under examination are directed to ***resorbable*** stent technology. That is, the stents themselves "can be both dissolved in and biologically assimilated by a patient." *See* page 8, lines 17-18. In contrast, while Lau describes instravascular stents, the ***stents of Lau are not resorbable***. As discussed in column 9, lines 58-60, the stents of Lau have a radially rigid structure such as those constructed of a network of radially rigid rings. Such rings, as discussed in column 12, lines 30-39, are made from nonresorbable materials such as metallic, super elastic alloys. Thus, Lau does not disclose ***resorbable*** stents, and applicants request withdrawal of this rejection.

THE 35 U.S.C. §102(B) REJECTION OVER RHEE ET AL.:

Similarly, Claims 1, 12, 28-33, 35 and 39, stand rejected under 35 U.S.C. §102(b) as anticipated by Rhee et al. According to the Examiner, Rhee et al. discloses a stent comprising polyethylene glycol conjugated to a collagenic material of gelatin, glycosaminoglycan polysaccharide or hyaluronic acid. As is the case with Lau, the Examiner recognizes that Rhee et al. does not expressly disclose the element regarding the resorbability time associated with the stent but nevertheless contends that the material described in Rhee et al. "is the same as claimed and inherently ... will function in the same fashion."

In response, applicants point out Rhee et al. contains no disclosure relating to ***resorbable*** stent technology. Instead, Rhee et al. is generally directed to compositions for use as bioadhesives, for tissue augmentation, for preventing surgical adhesions, and for coating surfaces of synthetic implants. *See, e.g.*, column 1, lines 13-20. That is, there is no teaching that the material can be made into a stent for insertion into an opening in a lumen of vessel or tissue of a patient. Instead, the only disclosure with respect to the use of the composition in connection with implantable technology is as a ***coating*** for a synthetic implant,

e.g. breast implants and lenticules. *See, e.g.*, column 19, lines 51-63. Applicants submit that synthetic implants such as breast implants and lenticules are ordinary consider nonresorbable, and that Rhee et al. contains no disclosure to the contrary. Thus, Rhee et al., like Lau, does not disclose ***resorbable*** stents, and applicants request withdrawal of this rejection as well.

THE 35 U.S.C. §102(B) REJECTION OVER MCGREEVY ET AL.:

Claims 1, 2, 12, 21, and 25 stand rejected under 35 U.S.C. §102(b) as anticipated by McGreevy et al. Without further elaboration and citing column 2, lines 66, to column 3, line 11 and column 3, lines 37-50, the Examiner characterizes McGreevy et al. as disclosing a stent comprised of physiologic saline that absorbs within 10 days.

Applicants traverse this rejection because the stent described in McGreevy et al. is comprised of an ***integral solid*** of a biological fluid material. *See, e.g.,* Abstract and FIG. 1. Unlike the stents recited in the pending claims, the stent of McGreevy does not have ***an opening at each of first and second termini and a primary lumen that provides fluid communication between the openings***. Thus, this rejection was issued in error, and applicants respectfully request withdrawal thereof.

THE 35 U.S.C. §103(A) REJECTION OVER NASH ET AL. IN VIEW OF SKEIE ET AL.:

Claims 1-5, 8, 17, 18, 20, 41-43, and 53 stand rejected under 35 U.S.C. §103(a) as obvious over Nash et al. in view Skeie et al. In support of this rejection, the Examiner states that Nash et al. discloses the claimed invention except for the specific resorbable material. To provide the admittedly missing teaching, the Examiner cites Skeie et al., column 3, line 18, to column 4 line 23, as teaching a resorbable material comprised of polyethylene glycol conjugated with a naturally occurring compound that is used for an anastomosis stent.

Applicants traverse this rejection because the criteria for establishing *prima facie* obviousness have not been met. *Prima facie* obviousness first requires some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference's teaching or to combine the teachings of two or more references. Second, there must be a reasonable expectation of success, and third, the prior art reference, or references when combined, must teach or suggest all the claim limitations. The teaching or suggestion to make the modification and the reasonable expectation of success must both be found in the prior art, and not based on an applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In addition, references must be read as a whole, including the portions that teach away from the claimed invention.

In this case, the cited patents provide generally incompatible disclosure and should not be read together. As an initial matter, Nash et al., is generally directed to anastomosis systems and methods of

using such systems rather than specifically to anastomosis stents. The connector associated with anastomosis system of Nash et al., as discussed in column 6, lines 17-19, does not require the use of any resorbable materials. In addition, it is taught that even when resorbable materials are used to form the anastomosis connectors of Nash et al., portions of the connectors may nevertheless be formed from nonresorbable materials. Applicants submit that if any nonresorbable material is used to form a stent, then the stent itself would not be resorbable. Thus, it should be evident that Nash et al. is primarily directed to nonresorbable technology. Indeed, Nash et al., column 6, lines 35-38, specifically teaches that stents are considered non-resorbable devices. Given that Nash et al. is generally directed to nonresorbable technology, one of ordinary skill in the art would not think to use the purportedly resorbable material of Skeie et al. to form the nonresorbable stent of Nash et al.

Furthermore, the cited patents do not teach all claim elements when read together. For example, it is described in Skeie et al. column 1, lines 43-55 that the material from which the prosthesis is formed must be susceptible to fragmentation. That is, the prosthesis must be crushed to facilitate its removal or degradation in a patient's body. *See* column 3, lines 18-26. It logically follows from this disclosure, then, that the ***material from which the prosthesis of Skeie et al. is formed is not easily resorbable***. Otherwise, fragmentation would not be needed. Consequently, if one were to use the material of Skeie et al. to form the stent of Nash et al., the resulting stent would not be readily resorbable. That is, the resulting stent ***would not be resorbable by a patient within a time period in the range of about a few minutes up to about 90 days, and the stent***.

As the two cited patents fail to disclose or suggest all elements of the pending claims, withdrawal of this rejection is warranted and respectfully requested.

THE 35 U.S.C. §103(A) REJECTION OVER RHEE ET AL.:

Claims 9-11 stand rejected under 35 U.S.C. §103(a) as obvious over Rhee et al. In support of this rejection, the Examiner states that Rhee et al. discloses the invention, but admits that the patent does not disclose the dimensions of anastomosis stents. Nevertheless, the Examiner states that "a change in size is generally recognized as being within the level of ordinary skill in the art."

In response, applicants note that, as discussed above, Rhee et al. does not disclose resorbable stents. Instead, nonresorbable implants having a resorbable coating are taught. Given that the Examiner has admitted that the dimensions recited in claims 9-11 are also absent from Rhee et al., it is clear that Rhee et al. does not suggest a resorbable stent of any particular dimensions. Accordingly, applicants submit that the rejection was issued in error and request withdrawal of this rejection.

THE 35 U.S.C. §103(A) REJECTION OVER NASH ET AL. IN VIEW OF SKEIE ET AL. AND KNUDSON ET AL.:

Claim 19 stands rejected under 35 U.S.C. §103(a) as obvious over Nash et al. in view of Skeie et al. and Knudson et al. In support of this rejection, the Examiner repeats her characterizations of Nash et al. and Skeie et al. and states that these two patents disclose the claimed invention except for perpendicularly intersecting lumens. To provide the missing teaching, the Examiner points to Knudson et al., FIGS. 1A, 1B, 2A and 20 as depicting perpendicular lumens.

In response, applicants point out that Knudson et al. generally provides apparatuses for coronary artery bypass surgery and contains very little disclosure regarding stent technology. Instead, the patent merely mentions that "rigid conduits" may be employed to carry out coronary bypass surgery. Nowhere in the patent is resorption discussed. As such, Knudson et al. provides no disclosure to cure deficiencies of Nash et al. and Skeiei et al. That is, even if the three patents were properly read together, they do not teach a stent that ***would be resorbable by a patient within a time period in the range of about a few minutes up to about 90 days***.

Accordingly, the failure of these three patent to disclose or suggest all elements of the pending claims indicates that withdrawal of this rejection is warranted.

THE 35 U.S.C. §103(A) REJECTION OVER RHEE ET AL. IN VIEW OF KRANTZ ET AL.:

Claims 21-24 stand rejected under 35 U.S.C. §103(a) as as obvious over Rhee et al. in view of Krantz et al. According to the Examiner, Rhee et al. discloses the claimed invention except for the resorption time. The Examiner further contends that Krantz et al. teaches the adjustment of the composition of an anastomosis stent "to dissolve when it is no longer needed." As a result, the Examiner states that Rhee et al. and Krantz et al. render claims 21-24 obvious.

In response, applicants again point out that Rhee et al. is not directed to a resorbable stent *per se*, but is more generally directed to compositions for use to coat surfaces of synthetic implants. If these two patents were read together and the composition of Rhee et al. were adjusted in the manner purportedly taught in Krantz et al, a nonresorbable synthetic implant with a controllably resorbable coating would result. Thus, Krantz et al. fails to cure the deficiencies of Rhee et al. and the two patents do not render the claims obvious. Accordingly, withdrawal of this rejection is respectfully requested.

THE 35 U.S.C. §103(A) REJECTIONS OVER NASH ET AL., SKEIE ET AL., DETWEILER ET AL., AND, OPTIONALLY, WALLACE ET AL. OR MATSUDA ET AL.

The Examiner made a number of obviousness rejection under 35 U.S.C. §103(a) by citing Nash et al., Skeie et al. and Detweiler et al. For example, the Examiner contends claims 10 and 44 are obvious

over these three patents. While admitting that Nash et al. and Skeie et al. fail disclose the use of a tissue sealant, the Examiner nevertheless states that Detweiler et al. provides the missing teachings relating to the use of a tissue sealant. Similarly, claims 44-50, 94, and 96 stand rejected obvious over the three patents in further view of Wallace et al, wherein Wallace et al. is cited as providing missing teachings relating a tissue sealant with improved strength. Furthermore, claims 51 and 52 stand rejected over the same three patents in further view of Matsuda et al., wherein Matsuda et al. is cited as providing missing teachings relating to spray or injection application of tissue sealants.

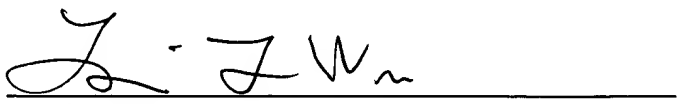
In response, applicants again point out that these rejections also exhibit the same failings as the above-discussed obviousness rejection over Nash et al. and Skeie et al. That is, Nash et al. and Skeie et al. ***cannot be properly read together*** and do not teach a stent that is ***resorbable by a patient within a time period in the range of about a few minutes up to about 90 days***. From applicants' review of Detweiler et al., Wallace et al., and Matsuda et al., none of these patents, either singly or in combination, cure the deficiencies of Nash et al. and Skeie et al. Thus, withdrawal of these rejections is respectfully requested as well.

CONCLUSION

For all of the above reasons, it is submitted that the application comports with all requirements of 35 U.S.C. §112, and that the pending claims define an invention that is patentable over the art. As the application should now be in condition for allowance, a prompt indication to that effect would be appreciated.

If the Examiner has any questions concerning this communication, she is welcome to contact the undersigned attorney at (650) 330-0900.

Respectfully submitted,

By: 

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